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10/574,101	03/08/2007	**Bernat Vidal Juan**	09605.0017	7472

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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	PAPER NUMBER
1624	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,101	VIDAL JUAN ET AL.	
	Examiner	Art Unit	
	/Venkataraman Balasubramanian/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-16,18 and 23* is/are allowed.

6)☒ Claim(s) *22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/7/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, which included cancellation of claim 21 and amendment to claim 22, filed on 1/7/2009, is made of record. Claims 1-16, 18, 22 and 23 are now pending. In view of applicants' response, the following 112 first paragraph scope of enbalment rejection of claim 22 made in the previous office action is maintained.

Information Disclosure Statement

References cited in the Information Disclosure Statements, filed on 3/31/2006 & 7/11/2006, are made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under U.S.C. 112, first paragraph, because the specification while being enabling for treating hypertension, asthma, bronchoconstriction, hypertension, reperfusion injury, myocardial ischemia, retinopathy and diabetes mellitus, does not reasonably provide enablement for treating a subject afflicted with a pathological condition or disease susceptible to amelioration by antagonism of the A_{2B} adenosine receptor including allergic diseases, hypertension, atherosclerosis, inflammation, cell proliferation disorders, and autoimmune diseases. The specification does not enable any physician skilled in the art of medicine, to use the invention commensurate in scope with the claim.

Many factors require consideration when determining whether sufficient evidence supports a conclusion that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue." See MPEP 2164.01(a).

The factors to be considered in making an enablement rejection have been summarized below.

In evaluating the enablement question, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention:

Therapeutic use of the compounds in treating pathological disorders/diseases that require A_{2B} adenosine receptor inhibitory activity. The instant method of use claim 22 is drawn to treating a subject afflicted with a pathological condition or disease susceptible to amelioration by antagonism of the A_{2B} adenosine receptor including allergic diseases, inflammation, cell proliferation disorders and autoimmune diseases. by inhibiting the activity of A_{2B} adenosine receptor for which there is no enabling disclosure.

Instant claim 22, as recited, is a reach through claim. A reach through claim is a claim drawn to a mechanistic, receptor binding or enzymatic functionality in general

format and thereby reach through a scope of invention for which they lack adequate written description and enabling disclosure in the specification.

In the instant case, based on the inhibition of A_{2B} adenosine receptor in general by the instant compounds, claim 22 reach through treating any or all pathological conditions and diseases mediated by A_{2B} adenosine receptor indicated above and thereby they lack adequate written description and enabling disclosure in the specification.

More specifically, in the instant case, based on the mode of action of instant compounds as inhibitor of A_{2B} adenosine receptor, based on limited in vitro assay with limited enzyme, it is claimed that treating any or all allergic diseases, inflammation, cell proliferation disorders, and autoimmune diseases. for which there is no enabling disclosure.

In addition, the scope of the claim is not adequately enabled solely based on the activity of the compounds provided in the specification at pages 1-2 and 14-17. The instant compounds are disclosed to have A_{2B} adenosine receptor inhibitory activity and it is recited that the instant compounds are therefore useful in treating any or all diseases stated above for which applicants provide no competent evidence. It appears that the applicants are asserting that the embraced compounds because of their mode action A_{2B} adenosine receptor inhibitor that would be useful for all sorts of generic diseases and disorders, including allergic diseases, inflammation, cell proliferation disorders and autoimmune diseases. However, the applicants have not provided any competent evidence that the instantly disclosed tests are highly predictive for all the

uses disclosed and embraced by the claim language for the intended host. Moreover many if not most of diseases such as lupus, Alzheimer's disease Parkinson's disease, multiple sclerosis etc. are very difficult to treat and despite the fact that there are many drugs, which can be used for "inflammatory condition".

The scope of the claims involves all of the millions of compounds of claim 1 as well as the thousands and thousands of diseases embraced in claim 22.

Similarly, enablement for the scope of "inflammation" generally is not present. For a compound or genus to be effective against inflammation generally is contrary to medical science. Inflammation is a process, which can take place individually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the inflammatory reaction. There is no common mechanism by which all, or even most, inflammations arise. Mediators include bradykinin, serotonin, C3a, C5a, histamine, assorted leukotrienes and cytokines, and many, many others. Accordingly, treatments for inflammation are normally tailored to the particular type of inflammation present, as there is no, and there can be no "magic bullet" against inflammation generally. Inflammation is the reaction of vascularized tissue to local injury; it is the name given to the stereotyped ways tissues respond to noxious stimuli. These occur in two fundamentally different types. Acute inflammation is the response to recent or continuing injury. The principal features are dilatation and leaking of vessels, and recruitment of circulating neurophils. Chronic inflammation or "late-phase inflammation" is a response to prolonged problems, orchestrated by T-helper lymphocytes. It may feature recruitment and activation of T- and B-lymphocytes,

macrophages, eosinophils, and/or fibroblasts. The hallmark of chronic inflammation is infiltration of tissue with mononuclear inflammatory cells. Granulomas are seen in certain chronic inflammation situations. They are clusters of macrophages, which have stuck tightly together, typically to wall something off. Granulomas can form with foreign bodies such as aspirated food, toxocara, silicone injections, and splinters. Otitis media is an inflammation of the lining of the middle ear and is commonly caused by Streptococcus pneumoniae and Haemophilus influenzae. Cystitis is an inflammation of the bladder, usually caused by bacteria. Blepharitis is a chronic inflammation of the eyelids that is caused by a staphylococcus. Dacryocystitis is inflammation of the tear sac, and usually occurs after a long-term obstruction of the nasolacrimal duct and is caused by staphylococci or streptococci. Preseptal cellulitis is inflammation of the tissues around the eye, and Orbital cellulitis is an inflammatory process involving the layer of tissue that separates the eye itself from the eyelid. These life-threatening infections usually arise from staphylococcus. Hence, these types of inflammations are treated with antibiotics. Certain types of anti-inflammatory agents, such as non-steroidal anti-inflammatory medications (Ibuprofen and naproxen) along with muscle relaxants can be used in the non-bacterial cases. The above list is by no means complete, but demonstrates the extraordinary breadth of causes, mechanisms and treatment (or lack thereof) for inflammation. It establishes that it is not reasonable to any agent to be able to treat inflammation generally.

The same applies to autoimmune diseases. The “autoimmune diseases” are a process that can take place in virtually any part of the body. There is a vast range of

forms that it can take,' causes for the problem, and biochemical pathways that mediate the inflammatory reaction. There are hundreds such diseases, which have fundamentally different mechanisms and different underlying causes. Thus, the scope of claims is extremely broad.

The claims cover methods for treatment of all of the diseases mentioned above, including other diseases that may be discovered in the future that may be comprehended under the recited diseases.

No compound has ever been found to treat any or all diseases and disorders and cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "compound" is contrary to our present understanding of modern medicine. The specification fails to identify the results of treatment with the methods of this invention and how such results would be recognized, particularly with regard to conditions and diseases that are currently considered incurable, untreatable or fatal.

Note substantiation of utility and its scope is required when utility is "speculative", "sufficiently unusual" or not provided. See Ex parte Jovanovics, 211 USPQ 907, 909; In re Langer 183 USPQ 288. Also note Hoffman v. Klaus 9 USPQ 2d 1657 and Ex parte Powers 220 USPQ 925 regarding type of testing needed to support in vivo uses.

Next, applicant's attention is drawn to the Revised Interim Utility and Written Description Guidelines, at 64 FR 71427 and 71440 (December 21, 1999) wherein it is emphasized that 'a claimed invention must have a specific and substantial utility'. The disclosure in the instant case is not sufficient to enable the instantly claimed method

treating solely based on the inhibitory activity disclosed for the compounds. The state of the art is indicative of the requirement for undue experimentation.

Also, note MPEP 2164.08(b) which states that claims that read on "... significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative.". Clearly that is the case here.

2) The state of the prior art: Recent publications expressed that the A_{2B} adenisone receptor inhibition effects are unpredictable and are still exploratory. See Sitkovsky et al., British Journal of Pharmacology, 153, 5457-5464, 2008, especially the concluding paragraph. See also Gao et al., Expert. Opin. Emerging Drugs 12(3): 479-492, 2008, which indicates the state of the art and points out need for further experimentation to establish the usefulness of antagonists of A_{2B} adenosine receptors.

3) The predictability or lack thereof in the art: Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating any or all allergic diseases, inflammation, cell proliferation disorders, and autoimmune diseases with the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, “the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved”. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present and 5) the presence or absence of working examples: Specification has no working examples to show treating any or all condition and diseases stated above and the state of the art is that the effects of adenosine receptor inhibitors are unpredictable.

6) The breadth of the claims: The instant claims embrace any or all allergic diseases, hypertension, atherosclerosis, inflammation, cell proliferation disorders, and autoimmune diseases including those yet to be related to A_{2B} adenosine receptor activity.

7) The quantity of experimentation needed would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the pharmaceutical use, for the reasons stated above.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of enzyme-inhibitor interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards treating the variety of diseases of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was 'filed, would not have taught one skilled in the art how to make

and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

This rejection is same as made in the previous office action but now excludes cancelled claim 21 and is limited to generic diseases cited above. Applicants' traversal to overcome this rejection is not persuasive.

First of all, as noted above, instant claim 22, as recited, is a reach through claim. A reach through claim is a claim drawn to a mechanistic, receptor binding or enzymatic functionality in general format and thereby reach through a scope of invention for which they lack adequate written description and enabling disclosure in the specification.

In the instant case, based on the inhibition of A_{2B} adenosine receptor activity by the instant compounds, instant claim reaches through inhibiting any or all kinases and treating any or all allergic diseases, inflammation, cell proliferation disorders, and autoimmune diseases in general and thereby they lack adequate written description and enabling disclosure in the specification.

More specifically, in the instant case, based on the mode of action of instant compounds as inhibitor of A_{2B} adenosine receptor activity, based on limited assays, it is claimed that treating any or all allergic diseases, inflammation, cell proliferation disorders, and autoimmune diseases in general for which there is no enabling disclosure. It is not the breadth the claim it is the scope of enablement that is being addressed.

In the present case, specification has no objective enablement for any or all diseases mediated by A_{2B} adenosine receptor activity in general. Contrary to applicants urging, with the genus of compounds and large list of diseases, one trained in the art had to extensively undue experimentation.

Again, it is not the objective enablement of genus of compounds is being addressed in the rejection. It is the scope of enablement for any or all diseases embraced in the claim language.

As for the traversal, again, applicants have not provided any direct evidence that the based on the mode of action of instant compounds, any or all indication can be treated including various diseases. Again, applicants' argument asserts the mode of action of the instant compounds as A_{2B} adenosine receptor activity inhibitors is shown in the specification but there is no direct evidence presented to show any or all diseases cited above can be treated because of the stated mode of action.

Applicants appears to assert that treating any or all diseases/disorders stated above with A_{2B} adenosine receptor activity inhibitors is known in the art but have not provided such a reference teaching treating any or all diseases with any kinase. Since, search in the related art did not suggest such an assertion, applicants should provide the literature showing treating any or all diseases/disorders by kinase inhibitors.

Furthermore, the references relied on by the applicants (cited in the Information Disclosure Statement dated 1/7/2009) also do not lend support to the notion that based on mode of action any or all diseases cited above can be treated.

Contrary to applicants' urging, given the large genus and large genus of diseases and disorders embraced in the claim language, one trained in the art need to unduly extensive experimentation without and then he need to assign the finding as applicants' invention for want of any guidance in the specification.

Applicants have not demonstrated nor have they alleged there is any correlation between the in vitro assays they disclosed in pages 13-16 and efficacy against all diseases including allergic diseases, inflammation, cell proliferation disorders, and autoimmune diseases. In an unpredictable art, such as cancer therapy (a cell proliferative disorder), in vitro assays may be used for enablement only if there is a well-established correlation between the assay and clinical efficacy. Several case laws lend support to the notion that merely establishing the mode of action of a class of compounds does not provide for scope of objective enablement for any or all diseases.

The issue in Ex parte Balzarini 21 USPQ2d 1892 concerned HIV treatment and the Board of Patent Appeals and Interferences wrote "While the in vitro testing performed on these anti-viral compounds appears to be useful as a screening tool in order to determine which of these anti-viral compounds are candidates for further testing to determine if they possess in vivo utility, the in vitro tests were not predictive of in vivo efficacy."

The issue in Fujikawa v. Wattanasin 39 USPQ2d 1895 was adequacy of in vitro testing of inhibitors of cholesterol biosynthesis and U.S. Court of Appeals Federal Circuit wrote, "in vitro results, in combination with a known correlation between such in

vitro results and in vivo activity, may be sufficient to establish practical utility". Such a correlation does not exist in the art of cancer therapy employing CDK2 inhibitors.

In a peripheral issue involving assaying insulin-like growth factor-I ("IGF- I") in Genentech Inc. v. Chiron Corp. 55 USPQ2d 1636, U.S. Court of Appeals Federal Circuit wrote "by the critical date, ... [s]pecific binding in an RRA was known by those skilled in the art to be reasonably correlated with the in vivo biological activity of IGF-I."

In Ex parte Bhide 42 USPQ2d 1441, the Board of Patent Appeals and Interferences wrote "While in vitro or in vivo tests would not be the only possible way to overcome our basis for questioning applicants' utility, in vitro or in vivo tests certainly would provide relevant evidence". The issue in the present case is not the utility of applicants' compounds, which was at issue in Ex parte Bhide 42 USPQ2d 1441, but rather the narrower issue of enablement for claims drawn to the treatment of all cancers. Since such a claim is inherently not credible, the standard of proof required for such an assertion must be high.

In a case concerning a DNA sequence encoding a mature human IL-3 protein, Ex parte Anderson 30 USPQ2d 1866, the Board of Patent Appeals and Interferences wrote in passing "We question whether one skilled in the art would accept appellants' in vitro test as predictive of in vivo results and whether one skilled in the art would know how to use the Pro (8) protein made .... Should the claims of this application be prosecuted further in a continuing application we urge the examiner to consider the enablement and utility aspects of patentabilityi" In an anti-tumor application, Ex parte Aggarwal 23 USPQ2d 1334, the Board of Patent Appeals and Interferences wrote

"there is considerable doubt that those skilled in the art would be willing to accept appellants' in vitro tests and in vivo tests as established models predictive of utility against tumors in humans. See In re Jolles, 628 F.2d 1322, 206 USPQ 885 The examiner had more than adequate reason to doubt the objective truth of the broad statement of utility set forth in appellants' specification." In the most definitive finding on this issue of the adequacy of in vitro assays for clinical claims, Ex parte Stevens 16 USPQ2d 1379 the Board of Patent Appeals and Interferences wrote "The examiner's position is based on the supposition that the facts described above evidence a prima facie case of nonenablement with regard to the disclosed utility in light of all the applicable legal precedents. Where as here, the disclosed utility is the treatment of cancer, we agree with this supposition. The examiner has cited Ex parte Busse, 1 USPQ2d 1908. In that case, the Board of Patent Appeals and Interferences reviewed the relevant prior decisions of its reviewing court. We shall not repeat those citations here. Suffice it to say that in every cited case the narrow issue involved was whether or not the evidence of record was based on in vivo or in vitro studies which were generally recognized by those of ordinary skill in the art as being reasonably predictive of success in the practical utility under consideration, i.e., human or, at least, mammalian therapy."

In a vaccine case, Ex parte Maas 14 USPQ2d 1762, the Board of Patent Appeals and Interferences wrote "First, although appellants' specification describes certain in vitro experiments, there is no correlation on this record between in vitro experiments and a practical utility in currently available form for humans or animals. It is not enough to rely on in vitro studies where, as here, a person having ordinary skill in the art has no

basis for perceiving those studies as constituting recognized screening procedures with clear relevance to utility in humans or animals. The burden is on appellants to establish the significance of the in vitro experiments set forth in their specification."

None of the state of the art references cited above and cited in the specification expressed a single therapeutic approach for the treatment of all diseases embraced in the instant claim 22 generally by administering a single class of compounds. Further, the state of the art not indicative of the fact that treatment of all types of diseases mediated by A_{2B} adenosine receptor activity is conventional or well known. Moreover, the findings and conclusions in the cited publications with respect to inhibition of A_{2B} adenosine receptor activity and the application of such activity for specific types of diseases do not lend support for treating all diseases. The instant claims, on the other hand, are drawn to several types of diseases affecting different organs and having different methods of growth or harm to the body, and different vulnerabilities.

However, the specification does not enable any physician skilled in the art of medicine, to use the compound of the invention commensurate in scope with the claims. The specification does not describe administration procedures and ranges of dosage regimen. The method of administration and/or the dose levels depend on a number of factors, which have to be evaluated by one of ordinary skill in the art. These factors include a) determining which of the claimed compounds would treat any particular claimed disease; b) synthesize the compound; c) formulate into a suitable dosage form depending the type of administration method; and d) conduct clinical trials or test the compound in an assay known to be correlated to clinical efficacy of such treatment. The

specification pages 13-17 provide assays to determine the activity of the compounds and nothing more. Applicants have not asserted that it is art recognized that the assays are correlated to clinical efficacy for treatment of all indication mediated by A_{2B} adenosine receptor activity. There is no working example of treatment of any disease in man or animal. The state of the clinical arts in does not provide any agent which effective against all indication in general or those indication mediated by any or all kinase. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of in vivo efficacy by those skilled in the art. See for example In re Ruskin 148 USPQ 221; Exparte Jovanovics 211 USPQ 907.

Based on the fact situation of the instant application, In re Buting, 163 USPQ 689 (CCPA 1969) (cited in the previous office actions) is on point and more applicable to the instant claims wherein 'evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of the claims directed to disparate types of cancers. The judges in that case indicated that "We are not aware of any reputable authority which would accept appellant's two clinical cases as establishing utility for treatment of cancer in humans. As was pointed out in Brenner v. Manson, 148 USPQ 689, a process to be patentable must produce a useful result and be of substantial utility not merely of scientific interest or for further testing. In this case further testing seems necessary".

In summary, applicants have not provided any evidence of record that the instantly claimed compounds can effectively be used in the treatment of all allergic

diseases, inflammation, cell proliferation disorders, and autoimmune diseases mediated by A_{2B} adenosine receptor activity in general and therefore, it is maintained that one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Hence, this rejection is proper and is maintained.

Allowable Subject Matter

Claims 1-16, 18 and 23 are free of prior art and are allowed, barring finding of any prior art in a subsequent search.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from

8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624